

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/819,308	NOTEBORN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph T. Voitach	1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/7/2004.
2. ☒ The allowed claim(s) is/are 15,16 and 19-21.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☒ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

This application filed March 27, 2001 claims benefit to foreign application 00201108.8 filed March 27, 2000 with European Patent Office.

Applicants' amendment filed September 2, 2004, has been received and entered. Claims 15 and 19 have been amended. Claims 15, 16, 19, 20 and 21 are pending and currently under examination.

### ***Election/Restriction***

As indicated previously, Groups VII and VIII were rejoined because it was Examiner indicated that a search of SEQ ID NO: 9 would identify partial sequences as encompassed by SEQ ID NO: 1, and thus, would not constitute an undue burden. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

As indicated previously claims 15, 16 and 19-21 are free of the art of record. The amendments to the claims have addressed and obviated the remaining rejection of record made under 35 USC 112, second paragraph. The present invention is based in part on the observation that SEQ ID NOs: 1 and 9 when administered and expressed in a cell induce apoptosis in said cell. Interestingly, the expression of SEQ ID NOs: 1 and 9 induces apoptosis in malignant and transformed cell lines, both p53 positive and p53 negative, however does not appear to affect

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many normal cell types. The specific activity of the protein encoded by SEQ ID NOs: 1 and 9 that induces apoptosis is not known, however the present specification teaches that the difference in localization of the protein in a transformed versus a non-transformed cell is different, in the nucleus versus the cytoplasm, respectively. Given the working examples in the present specification demonstrating the apoptotic affect of SEQ ID NOs: 1 and 9 expressed in transformed cell types, there clear support for inducing apoptosis in a cell, and a reasonable expectation that this affect would occur *in vivo* when administered to a transformed cell.

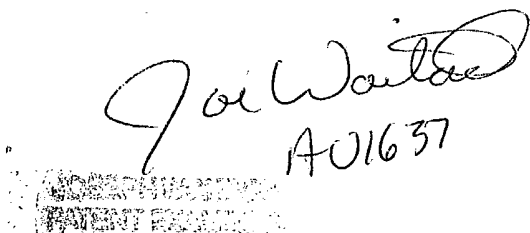
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

  
A01637  
PATENT EXAMINER